

EXHIBIT 5

CERTIFICATE OF NEED REVIEW REPORT
CN1605-021 East Tennessee Healthcare Holding, Inc.

Submitted by
Mountain States Health Alliance
303 Med Tech Parkway, Suite 330
Johnson City, TN 37604

Application date June 1, 2016

The Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS) has reviewed the application for a Certificate of Need (CON) submitted by Mountain States Health Alliance for a non-residential (outpatient) opioid treatment program (for adult patients who are addicted to/dependent on opioid substances) to be owned by East Tennessee Healthcare Holdings, Inc. and located in Johnson City, Tennessee, Washington County. In accordance with rules of the Tennessee Health Services Development Agency (HSDA), the Department's analysis consists of the following three components: Need, Economic Feasibility, and Contribution to the Orderly Development of Health Care.

This review consists of three (3) parts:

- Scope of Project
- Analysis of Need, Economic Feasibility and Contribution to the Orderly Development of Health Care
- Conclusions

SCOPE OF PROJECT

The Mountain States Health Alliance (MSHA) and East Tennessee State University (ETSU) have formed a not-for-profit corporation, East Tennessee Healthcare Holdings, Inc. (ETHHI). ETHHI is requesting approval of a Certificate of Need for a non-residential (outpatient) substitution-based treatment program (OTP) for adult patients who are addicted to/dependent on opiates. The proposed location is 203 Gray Commons Circle, Johnson City, TN in approximately 7,851 square feet of medical office space to be redesigned for an opioid treatment program. The site is owned by Mountain States Properties, Inc. and was previously leased to MSHA's medical management group for a family practice and urgent care. Locating the proposed OTP at this site would require re-zoning.

The site is approximately 1 mile west from exit 13 of 1-26 on TN-75 S. Bobby Hicks Highway/Suncrest Drive. The Gray Commons commercial development includes 38.8 acres of developable land (MSHA owns 36.2 acres and the City of Johnson City owns 2.6 acres). The only other lot developed to date is occupied by Johnson City Fire Station 8 in a lot across the street from the proposed program site. Gray Commons is otherwise surrounded by vacant land. Daniel Boone High School is located approximately 1.5 miles further west on TN-75/Suncrest Drive. The estimate renovation cost of \$1,747,777 is to be paid from MSHA cash reserves.

The proposed service area includes eight Tennessee counties corresponding to the TDMHSAS Planning Region I (Carter, Greene, Hancock, Johnson, Sullivan, Unicoi and Washington counties), three Virginia counties (Lee, Scott and Washington) and the locality of Bristol City, VA. The OTP is described as being one component of ETSU's Center for Prescription Drug Abuse Prevention and Treatment (pp. 8, 13 initial application). The applicant describes the ETHHI strategy as combining clinically valid treatment options with comprehensive services including counseling and support services (e.g. facilitating employment and housing). The applicant indicates that the Center will also provide clinical training, community education and outreach, and practical research and evaluation funded by grants awarded to ETSU. The applicant intends to partner with Frontier Health for therapy and recovery services to augment the opioid replacement services provided by the OTP, and the applicant intends to contract directly with Frontier for 5.0 FTEs of licensed and unlicensed therapists to provide on-site counseling and smooth the referral process for additional Frontier co-occurring services (see Working Relationships with Existing Health Care Providers, p. 8, below).

The OTP intends to focus on implementing operations for methadone replacement treatment during the first two years of operation and estimates that the use of buprenorphine would be implemented on a case-by-case basis as clinically indicated beginning in the third year. The applicant estimates serving 650 patients in the first year and 1,050 patients the second year. The cost of the service will be \$13 per patient per day. The applicant estimates operating at a loss of \$326,421 in the first year and a positive bottom line of \$956,425 the second year. The proposed OTP will have operating hours Monday through Friday, 5:00 am – 3:00 pm Saturday and Sunday, 6:00 am – 9:30 am. The early morning hours are intended to accommodate patients who are employed full time.

The applicant states that the long-term goal of the project is to “develop a comprehensive, innovative, holistic model of care for this patient population by bringing together the local academic and research resources of ETSU coupled with the medical care expertise and capital resources of MSHA (p. 7, initial application).”

ANALYSIS

A. NEED

1. A description of the geographic area to be served:

The proposed service area includes eight Tennessee counties corresponding to the TDMHSAS Planning Region I (Carter, Greene, Hancock, Johnson, Sullivan, Unicoi and Washington counties), three Virginia counties (Lee, Scott and Washington) and the locality of Bristol City, VA.

2. An analysis of the population of the area:

The applicant provides population estimates for each of the counties in the proposed service area, including 2016 estimates and projected 2020 estimates (including the Virginia localities). The total Tennessee service area estimates of 516,768 for 2016 and 538,738 for 2020 are generally consistent with estimates from the Center for Business and Economic Research (CBER), University of Tennessee, Knoxville (the

applicant's estimates for Carter County are 2% lower than the CBER in 2016 and 4% lower for 2020, which could result in a slight underestimate of need for that county).

3. The estimated number of persons in the described area who are addicted to heroin or other opioid drugs and an explanation of the basis of the estimate:

The applicant provides a chart compiling the data reported by the State Epidemiology Outcomes Workgroup (which includes the Department of Health, the TDMHSAS, Vanderbilt and East Tennessee State Universities, among others) showing significant increases beginning in 2011-2012 through 2014 in drug seizures, admissions to TDMHSAS substance abuse treatment services, crimes, arrests and drug poisonings associated with heroin abuse. The applicant also cites the estimated rate of adults addicted to opioid prescription drugs reported in "Prescription for Success: Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee" (created in part by the TDMHSAS) and applies that rate to the population counts from the proposed service area, resulting in an estimate of "29,000 individuals are in need of early intervention or treatment for addition to prescription opioids (p. 27)." In response to a request from the HSDA for clarification on the reference to early intervention, the applicant indicated that the larger proposed Center would provide early intervention strategies to a broader range of patients in addition to those receiving medical treatment through the OTP, and that the estimate of patient need for the OTP was based on an actual state patient count of patients being served by existing OTPs to the proposed service area (p. 5, Supplemental #1).

For that estimate the applicant cites a TDMHSAS 2012 report indicating that 9,221 Tennessee residents sought treatment at an OTP, which is a rate of 145 per 100,000 based on a state-wide population count of 6,361,070. This would be 932 patients for the entire proposed services area (TN and VA) for a 2016 population estimate of 643,005 and 950 patients for a 2020 population estimate of 655,045 (for the Tennessee area only, that would be 749 patients for 2016 and 781 for 2020).

The applicant goes on to suggest (pp. 41-42) that the rate of 145 per 100,000 may not adequately account for the rate of increase in indicators of heroin and prescription drug abuse and dependence, or for the likelihood that there are a number of people in the proposed service area who would be appropriate for OTP services who are not in treatment currently because of the distance to existing OTPs. The applicant suggests an estimate of 165 per 100,000 would be more accurate. Based on that rate, the applicant provides the following estimates of the potential patient pool and the proposed number of patients to be served in year one (2018) and year two (2019) of the program's operation:

	Total Patient Pool		Total Projected Patients	
	Yr. 1 2018	Yr. 2 2019	Yr. 1 2018	Yr. 2 2019
Tennessee	879	882	534	863
Virginia	191	191	116	187
Total	1,070	1,073	650	1,050

The TDMHSAS prevalence estimates show that, for the Region in which the service area is located, 4.6% of adults used non-medical pain relievers. Present percentages of adults using non-medical pain relievers in 2015 (using 2012 percentage of 4.6%) results in 18,522 for the service area. This does not represent the number of people needing treatment, only the number of people using opioids non-medically.

If 18,552 individuals report the non-medical use of pain relievers, an estimated 2,600 individuals or 14% would meet the criteria for substance abuse treatment based on estimates of the National Institute for Drug Abuse indicates on its website (www.drugabuse.gov/publications/research-reports/prescription-drugs/director). It is unknown what percentage of those 2,600 would be addicted to opiates and would be candidates for opioid substitution treatment such as methadone maintenance or buprenorphine-assisted treatment. As noted above, the applicant's estimate of total patient pool in the Tennessee counties based on a rate of 165 patients per 100,000 residents in year one of operation (2018) is 879 and in year 2 (2019) is 882. These appear to be reasonable estimates based on known rates of abuse and typical proportion of abusers appropriate for medication-assisted treatment.

4. The estimated number of persons in the described area addicted to heroin or other opioid drugs presently under treatment in methadone or other treatment programs:

The applicant notes that there currently is no methadone maintenance program in the proposed service area and reports utilization data from the three closest OTPs (two in Knoxville, one in Chattanooga). The utilization data was provided to the applicant upon request by the TDMHSAS and shows that 29 patients from the proposed service area are receiving treatment at the other OTPs. TDMHSAS-funded agencies reported 1,056 admissions in 2014 for the non-medical use of prescription opioids (1,019) or heroin (37) for the Tennessee counties in the proposed service area.

There is one approved CON for inpatient substance abuse services in the proposed service area. Strategic Behavioral Health has an approved CON for a 72-bed psychiatric and substance abuse facility which includes 10 beds for substance abuse detoxification services. This CON is not yet implemented and even when implemented it will not include methadone maintenance services.

5. Projected rate of intake and factors controlling intake:

The Applicant estimates an intake of as many as 60 patients per month during the first year, with factors controlling intake to include a mix of transfer patients currently in services and new patients (which require more time to admit).

6. Comparison of estimated need to existing capacity:

The applicant provides a chart of distance and drive times to the six nearest OTPs (including locations in Virginia, Kentucky and North Carolina as well as Knoxville, TN) to the proposed service area in direct comparison to the distance and drive times to the proposed location in Johnson City, TN to demonstrate how there is no existing capacity for methadone maintenance services for the proposed service area (pp. 34-35). The applicant acknowledges the presence of a number of buprenorphine providers in the area (estimated at 120, based on the Substance Abuse and Mental Health Services Association website) but reports that the intention of the proposed OTP is to meet the unmet need of

methadone substitution. The applicant estimates the need as just over 1,000 potential patients in the first year of operation with no existing capacity.

The applicant correctly notes that research indicates that methadone treatment has advantages over buprenorphine for patients with a high level of physical dependency while buprenorphine has advantages at moderate doses with less risk of overdose or abuse, and that the determination of which treatment is the best option must be made on a case-by-case basis. There is no empirical basis for estimating the proportion of patients better served by methadone replacement over buprenorphine. The applicant concludes that “(t)here is a role for both (methadone and buprenorphine) in the continuum of care for opioid addiction (Supplemental #1, p. 6)” and indicates that ESHHI intends to implement the availability of buprenorphine in year three of operation (2020) along with “broader elements of counseling, therapy, and recovery services (Supplemental #1, p. 10).”

B. ECONOMIC FEASIBILITY

1. Ownership and Management

Mountain States Health Alliance (MSHA) and East Tennessee State University (ETSU) have formed a not-for-profit corporation, East Tennessee Healthcare Holdings, Inc. (ETHHI) which will own and operate this proposed non-residential Opioid Treatment Program (OTP).

Mountain States Health Alliance is a tax-exempt entity with operations primarily located in Washington, Sullivan, Unicoi and Carter counties of Tennessee and Smyth, Wise, Dickenson, Russell and Washington counties of Virginia. The primary operations of the Alliance consist of eleven acute and specialty care hospitals.

The applicant indicates that ETSU received approval from the Tennessee Board of Regents to create the Center for Prescription Drug Abuse Prevention and treatment envisioned to include an Administrative Core, a Patient Care Core, a Research and Evaluation Core and an Education and Outreach Core (p.13, initial application). The OTP is proposed to be one program in the Patient Care Core along with Neonatal Abstinence Prevention and counseling, recovery and support services provided through existing programs offered by Frontier Health Services, Inc. Counselors will be housed in the OTP facility and staff from the additional components will be housed in space adjacent to the clinic.

2. Expected Costs and Alternatives; Revenue and Expense Information

The proposed location is 203 Gray Commons Circle, Johnson City, TN in approximately 7,851 square feet of medical office space to be redesigned for an opioid treatment program. The site is owned by Mountain States Properties, Inc. and was previously leased to MSHA’s medical management group for a family practice and urgent care. Use of this site would require local approval for re-zoning.

The site is approximately 1 mile west from exit 13 of I-26 on TN-75 S. Bobby Hicks Highway/Suncrest Drive. The Gray Commons commercial development includes 38.8 acres of developable land (MSHA owns 36.2 acres and the City of Johnson City owns 2.6 acres). The estimate renovation cost of \$1,747,777 is to be paid from MSHA cash reserves.

The floor plan enclosed with the application shows overall adequate space for the OTP and there are advantages to the site having previously been used as medical office space. However, it is not clear that the design allows for private dosing areas for each patient with a nurse who accesses the medicine in the pharmacy and can provide the dose directly to the patient without leaving the area. A common arrangement is for patients to enter a small private area from the lobby and address a nurse who is in the pharmacy area across a counter from the patient. This allows for a minimum of movement of the medicine while the nurse can directly observe the patient taking the medicine. Details of these or similar arrangements will need to be addressed during the development of the space.

The applicant does not intend to attempt to contract with TennCare during the first two years of operation in order to focus on initiating the operations of the clinic for self-pay clients and clients who qualify for charity care (p. 2, Supplement #1). The applicant bases the proposal on operation without TennCare contracts, though options for contracting in the future for those clients whose methadone might be covered by TennCare (ages 18-20) or for buprenorphine prescriptions and enhanced support services beginning in year 3 of operations are discussed (p. 31 of initial application, pp. 2-4 Supplement #1).

Revenues for the OTP are calculated on serving 650 patients during the first year of operation (staggering the start date for the patients) and 1,050 patients during the second year. Deductions include some provision for charity care and expenses are primarily in salaries and wages. The applicant projects to operate at a loss in the first year of \$326,421 with a positive bottom line of \$956,425 the second year.

C. CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE

1. Staffing and Treatment Information

The proposed staffing pattern shows adequate staffing of all clinical positions and strong staffing of medical coverage. A medical director will be half time the first year of operation and full time during the second year. There will be a full time on-site prescriber the first year and two full time positions the second year of operation. Nursing includes two full time RNs the first and second years with one full time LPN the first year and two the second year. The proposed pattern includes a full time program director of operations, therapists and indirect staff. The proposed staffing also includes a full time clinical pharmacist and a full time psychiatric nurse practitioner. The applicant provided target compensation for the staffing pattern which appears very competitive. There will be a total of 17 staff in place by the second full year of operation (p.8).

2. Effect on Existing Providers and Resources

The applicant notes that there are no methadone replacement providers in the proposed service area. The applicant provides a chart of distance and drive times to the six nearest OTPs (including locations in Virginia, Kentucky and North Carolina as well as Knoxville, TN) to the proposed service area in direct comparison to the distance and drive times to the proposed location in Johnson City, TN to demonstrate how there is no existing capacity for methadone maintenance services for the proposed service area (pp.

34-35). The applicant estimates the need as just over 1,000 potential patients in the first year of operation with no existing capacity.

The applicant acknowledges the presence of a number of buprenorphine providers in the area, estimated at 120, based on the Substance Abuse and Mental Health Services Association website. Physicians properly certified to prescribe buprenorphine have been limited to 30 patients the first year and then 100 patients, but a recent rule change by the Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration, would increase from 100 to 275 the number of patients that qualified physicians who prescribe buprenorphine for opioid use disorders can treat (change effective 8/8/2016 and includes additional requirements such as having been approved under a 100 patient limit for at least a year). Studies¹ conducted under the 100-patient limit found that 44%-66% of certified physicians actually prescribed buprenorphine, and the majority did not prescribe to their patient limit. The current proposal indicates the proposed OTP would provide only methadone during the first two years of operation with a primary objective to meet the unmet need of methadone substitution.

The agency Comprehensive Community Services in Johnson City, TN offers substance abuse services including adult outpatient and adult intensive outpatient services, residential services for adults and adolescents, but no methadone replacement services. The agency Families Free offers outpatient and intensive outpatient services for women including pregnant women, but again no methadone replacement services. As noted below (see 5. Working Relationship with Existing Health Care Providers), Frontier Health offers medically monitored withdrawal management in addition to a full range of substance abuse services. The proposed OTP program would not directly affect any of these existing providers and would add resources to the region.

3. Letters of Support

The applicant indicates that letters of support will be submitted directly to HSDA prior to the scheduled hearing (Supplemental #1, p. 20).

4. Implementation of State Health Plan

Healthy Lives: improving the health of people in Tennessee The proposed OTP is intended to provide methadone replacement treatment for people addicted to opioids, reducing the negative health effects of illicit use of prescription medicine and/or illicit drugs such as heroin, which often increases when access to prescription opioids is reduced through law enforcement and prescription monitoring procedures. Reduction in illicit opioid abuse also reduces associated health risks, such as disease associated with intravenous drug abuse. Methadone replacement treatment may be a temporary measure in an overall treatment course toward tapering medication assistance for a drug-free life, and is more likely to contribute to overall health when delivered in association with support services and additional clinical consultation available in the proposed Center for Prescription Drug Abuse and Treatment.

Access: improving access to health care and the conditions to achieve optimal health The proposed OTP is to be located in a region which does not currently have an

¹ Jones, C.M., Campopiano, M, Baldwin, G. & McCance-Katz, E. (2015) National and state treatment need and capacity for opioid agonist medication-assisted treatment. *American Journal of Public Health*, June 11, 2015.

OTP. The integration of the OTP with the Center for Prescription Drug Abuse and Treatment is intended to improve access to a range of drug abuse treatment and support services.

Economic Efficiencies: Health outcomes for patients of the proposed OTP are likely to be improved through integration with support services, prevention efforts, education, outreach, research and evaluation associated with the non-profit Center. This integrated approach is intended to improve economic efficiencies for OTP services above what a free-standing OTP could accomplish.

Quality of Care: the collaboration of Mountain States Health Alliance with the academic and professional expertise of the James H. Quillen College of Medicine at ETSU is a sound strategy to assure the quality of opioid abuse treatment services informed by the latest advancements in research and clinical care.

Workforce: The role of ETSU in the ETHHI project provides ample opportunity for the inclusion of trainees from a wide variety of health care professions in training on the prevention and treatment of substance abuse. Health care areas include medicine, pharmacy, nursing, counseling and social work. ETSU has established programs in the prevention and treatment of substance abuse. The applicant also notes that MHSA is already affiliated with the James H. Quillen College of Medicine at ETSU. This affiliation allows the staff of the proposed OTP to have access to the expertise of ETSU, supporting the maintenance of a well-trained opioid abuse treatment workforce.

5. Working Relationships with Existing Health Care Providers

As noted above, the primary operations of the Mountain States Health Alliance includes 11 acute and specialty care hospitals in the region, and the Alliance is already affiliated with the James H. Quillen College of Medicine at ETSU. The proposed OTP would include a working relationship with Frontier Health (pp. 7-8, Supplemental #1), a community mental health agency with locations in East Tennessee and Southwest Virginia offering a wide range of mental health and substance abuse services. Frontier Health's existing substance abuse services include adolescent day treatment and outpatient services, adult outpatient, intensive outpatient and residential services, medical/social detoxification, medically monitored withdrawal management, women's intensive outpatient services, pregnant women's services and HIV/AIDS outreach. According to the proposal, Frontier began an opioid replacement program in Virginia in 2004 which includes induction, stabilization and reduction phases with a goal of medication free recovery. The applicant intends to contract with Frontier Health for 5.0 FTEs of counseling staff to be on-site of the OTP to facilitate referral to additional services (p. 8, Supplemental #1).

CONCLUSIONS

1. The need for a non-residential opioid-treatment program as part of a comprehensive approach to opioid abuse and dependence in the proposed region has been reasonably established. The applicant's estimates of opioid abuse and dependence in the identified region appear to be based on reasonable assumptions and accepted data (e.g. known rates of methadone maintenance usage in other parts of the state and indications in the proposed region of rates of opioid abuse and dependence). The applicant correctly cites

the difference between survey rates of “risky prescription of opioid use” and likely rates of need for OTP services (p. 5, Supplemental #1).

2. The proposed project appears to be economically feasible. Proposed staffing meets or exceeds licensure requirements and proposed salaries are consistent with market rates. Costs for program development and budgeting appear reasonable and documentation supports the availability of needed capital for start-up. The proposal allows for operating at a loss in the first year with a positive bottom line beginning the second year.
3. The application for a non-residential opioid treatment program as part of a non-profit corporation operating a center with a comprehensive approach to prevention and treatment of drug abuse would contribute to the orderly development of health care in the state of Tennessee. As proposed, the non-profit East Tennessee Health Holdings, Inc. would combine the established health care delivery organization Mountain States Health Alliance with the academic and clinical expertise of East Tennessee State University, of which the OTP would be one service. The proposed partnership with Frontier Health, Inc. would establish an important relationship with an existing provider of comprehensive community mental health and substance abuse services and improve access to a range of substance abuse treatment to Tennesseans in this region struggling with opioid abuse and dependence.

Jeff Feix, Ph.D.
Director, Office of Forensic and Juvenile Court Services
Division of Planning, Research and Forensics
TDMHSAS